### UNITED STATES DISTRICT COURT EASTERN DISTRICT OF VIRGINIA NORFOLK DIVISION

IN RE: ZETIA (EZETIMIBE) ANTITRUST LITIGATION

MDL No. 2:18-md-2836

THIS DOCUMENT RELATES TO: ALL RETAILER CASES

2:18-cv-00266

2:18-cv-00423

2:18-cv-00439

BRIEF IN SUPPORT OF DEFENDANTS' JOINT MOTION TO DISMISS THE RETAILER PLAINTIFFS' COMPLAINTS

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### I. INTRODUCTION

While claiming to follow a well-traveled path to antitrust liability, each of the complaints filed in these actions seeks an unprecedented and unwarranted extension of antitrust scrutiny to a Hatch-Waxman patent litigation settlement between Merck <sup>1</sup> and Glenmark <sup>2</sup> concerning the active ingredient in the branded cholesterol drug, Zetia, in which no cash beyond litigation expenses was exchanged, there was no side deal, and Merck expressly retained multiple ways to compete with Glenmark during their period of statutory exclusivity. In addition to adopting this unprecedented theory of liability espoused by the class plaintiffs, the Retailer Plaintiffs go one step further by asserting, contrary to Supreme Court precedent, that the settlement at issue should be judged under the *per se* rule.<sup>3</sup> Retailer Plaintiffs' claims are legally defective and should be dismissed for the following reasons.

*First*, Count I of each of the Retailer Plaintiffs' Complaints—which purport to assert a *per se* violation of Section 1 of the Sherman Act—fails because the Supreme Court in *FTC v*.

Actavis, 570 U.S. 136, 158 (2013), conclusively foreclosed the application of the *per se* rule to

<sup>&</sup>quot;Merck" refers to Merck & Co., Inc., Merck Sharp & Dohme Corp., Schering-Plough Corp., Schering Corp., and MSP Singapore Co. LLC.

<sup>&</sup>lt;sup>2</sup> "Glenmark" refers to Glenmark Pharmaceuticals, Ltd. and Glenmark Generics Inc., USA, incorrectly identified as Glenmark Generics Inc., USA.

The Retailer Plaintiffs' Complaints were filed separately as: (1) Complaint and Demand for Jury Trial, *Walgreen Co., et al. v. Merck & Co.*, Civ. No. 2:18-cv-266 (E.D. Va. May 18, 2018), Dkt. No. 1 ("Walgreen Compl."); (2) Complaint and Demand for Jury Trial, *Rite Aid Corp. v. Merck & Co.*, Civ. No. 2:18-cv-423 (E.D. Va. Aug. 6, 2018), Dkt. No. 1 ("Rite Aid Compl."); and (3) Complaint and Demand for Jury Trial, *CVS Pharmacy v. Merck & Co.*, Civ. No. 2:18-cv-439 (E.D. Va. Aug. 13, 2018), Dkt. No. 1 ("CVS Compl.") (collectively, the "Complaints"). Retailer Plaintiffs opted not to file a single, consolidated amended complaint as contemplated in Pretrial Order No. 4 (Dkt. No. 106). Their complaints, however, contain virtually identical allegations and thus are addressed collectively in this motion.

so-called "reverse-payment" claims arising out of Hatch-Waxman patent settlements. Instead, the Court held without exception that the rule of reason controls such claims.

Second, Count II of each of the Retailer Plaintiffs' Complaints, which asserts Section 1 Sherman Act claims, is defective because Retailer Plaintiffs, like the class action plaintiffs, have failed to allege a "large and unjustified" reverse payment under *Actavis*. Retailer Plaintiffs' allegations that Merck and Glenmark entered into a no-authorized generic ("No-AG") agreement that impermissibly eliminated the risk of competition between the companies in an alleged market for branded and generic Zetia cannot be squared with the language of the Settlement Agreement. Because Retailer Plaintiffs have not plausibly alleged a "large and unjustified" payment that is consistent with the terms of the document on which their complaints are based, dismissal of Count II is required.

*Third*, Count III of Retailer Plaintiffs' Complaints fails as a matter of law because nowhere do they allege that any Defendant acted with specific intent to monopolize, as is required to state a cognizable claim for conspiracy to monopolize.

*Finally*, Retailer Plaintiffs' Complaints also should be dismissed insofar as they seek injunctive relief because Retailer Plaintiff have failed to allege ongoing or future harm as is required under Section 16 of the Clayton Act and Article III of the Constitution.

### II. ARGUMENT

- A. <u>Count I of the Complaints Should Be Dismissed Because Per Se Liability Is</u> <u>Unavailable in Reverse-Payment Cases.</u>
  - 1. Supreme Court Precedent Requires the Application of the Rule of Reason in Reverse-Payment Cases.

Not content with merely joining the class action plaintiffs in advancing a theory of antitrust liability that cannot be squared with the Settlement Agreement and that lacks support in the existing law, Retailer Plaintiffs take their claims one step further, alleging an "unlawful"

reverse-payment settlement agreement between Merck and Glenmark" that they claim should be analyzed under the *per se* rule. Walgreen Compl. ¶¶ 1, 220, 237-38; Rite Aid Compl. ¶¶ 1, 219, 236-37; CVS Compl. ¶¶ 1, 219, 236-37. But any such *per se* claim is clearly foreclosed by *Actavis*, in which the Supreme Court held that plaintiffs in reverse-payment cases must plead and prove their claims "as in other rule-of-reason cases." 570 U.S. at 159. Indeed, the FTC asked the Court in *Actavis* to apply a standard that is more rigorous than the rule of reason— i.e., a "quick look" approach under which reverse-payment settlements are "presumptively unlawful"—which the Court rejected. The Court explained that even a "quick look" analysis is "appropriate only where 'an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets." *Id.* (quoting *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999)).

Reverse-payment settlements do not, the Court held, "meet this criteria." *Id.* Instead, reverse-payment agreements often are procompetitive. For instance, "settlement on terms permitting the patent challenger to enter the market before the patent expires" would "bring about competition . . . to the consumer's benefit." *Actavis*, 520 U.S. at 154. And, of course, no anticompetitive harm can occur where a "reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services." *Id.* at 156. For that reason, the *Actavis* Court *refused* to hold that reverse-payment agreements are "presumptively unlawful" under a quick look approach, much less that such agreements are *per se* unlawful. Rather, an antitrust defendant must be permitted to "show in the antitrust proceeding that legitimate justifications are present." *Id.* at 156, 158-59; *see also State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997) ("we have expressed reluctance to adopt *per se* rules with regard to 'restraints imposed in the context of business relationships where the economic impact of certain practices

is not immediately obvious'" (quoting FTC v. Ind. Fed'n of Dentists, 476 U.S. 447, 458-459 (1986))).

Since the Actavis decision, courts have faithfully and uniformly applied the rule of reason to analyze so-called "reverse-payment" antitrust claims arising out of Hatch-Waxman patent settlements even where a "large and unjustified" payment has been adequately pled. E.g., In re Nexium (Esomeprazole) Antitrust Litig., 842 F.3d 34, 41-42 (1st Cir. 2016) (addressing Hatch-Waxman settlement with a "no-AG clause" and observing "the Supreme Court held that the potential anticompetitive effects of a reverse payment are subject to the antitrust 'rule of reason' test"); In re Lipitor Antitrust Litig., 855 F.3d 126, 136, 140 (3d Cir. 2017), as amended (Apr. 19, 2017) (describing Actavis's analysis of challenges to alleged reverse-payment agreements and explaining that "[s]uch antitrust questions are to be addressed under the traditional rule-of-reason analysis"); cf. State Oil Co., 522 U.S. at 10 ("most antitrust claims are analyzed under a 'rule of reason'"). Indeed, the court in *United Food & Commercial Workers Local 1776 & Participating* Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc., 74 F. Supp. 3d 1052 (N.D. Cal. 2014), specifically rejected plaintiff's analogous attempt to assert a per se claim arising out of an alleged no-AG clause, noting that "Actavis fundamentally altered the landscape and directed district courts to apply the rule of reason analysis to patent settlements." Id. at. 1075 (granting motion to dismiss). Because Actavis requires the application of the rule of reason to Retailer Plaintiffs' claims in all events, Count I of the Complaints alleging a per se antitrust violation must be dismissed.

# 2. Retailers' Invocation of the Phrase "Horizontal Market-Allocation" Does Not Trigger the *Per Se* Rule.

Notwithstanding the clear holding of *Actavis*, and the unanimity among lower courts that the rule of reason controls so-called "reverse-payment" claims, Retailer Plaintiffs ask this Court

to apply the *per se* rule here by labelling the challenged conduct as an "unlawful horizontal market-allocation agreement[] in which the relevant market is allocated temporally rather than geographically." Walgreens Compl. ¶ 1; Rite Aid Compl. ¶ 1; CVS Compl. ¶ 1. But even if the Supreme Court had not already spoken on the issue, Retailer Plaintiffs' use of those antitrust buzzwords would not justify *per se* treatment of Sherman Act Section 1 claims in these cases.

The *per se* rule only applies to a discrete set of business practices that courts presume to be anticompetitive given the obvious harm. *Nw. Wholesale Stationers, Inc. v. Pac. Stationery & Printing Co.*, 472 U.S. 284, 289 (1985) ("*per se* approach permits categorical judgments with respect to certain business practices that have proved to be predominantly anticompetitive"). Allegations of a reverse-payment agreement are not among this set of plainly anticompetitive business practices—in fact, alleged reverse-payment agreements are often found not to violate the Sherman Act at all. *See, e.g., FTC v. AbbVie Inc.*, 107 F. Supp. 3d 428, 436-37 (E.D. Pa. 2015) (finding that alleged reverse-payment agreement was "procompetitive" and granting defendants' motion to dismiss), *appeal docketed*, No. 18-2621 (3d Cir. July 23, 2018); *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734 (E.D. Pa. 2015) (conducting rule of reason analysis and granting summary judgment for defendants in reverse-payment case), *aff'd*, 868 F.3d 132 (3d Cir. 2017). In any case, "talismanic invocation" of the phrase "horizontal market-allocation agreement" does not "bring the *per se* rule to bear." *See Apex Oil Co. v. DiMauro*, 713 F. Supp. 587, 596 (S.D.N.Y. 1989).

In short, Retailer Plaintiffs cannot rely on artful pleading to sidestep the fact that the Supreme Court has spoken on the proper analytical framework to apply to Section 1 reverse-payment cases. *Actavis*, 570 U.S. at 159. Dismissal of Retailer Plaintiffs' purported *per se* claim asserted in Count I of the Complaints is therefore warranted.

### B. Retailer Plaintiffs' Claims In Counts II and III Fail For the Same Reasons That Direct Purchaser Plaintiffs' Claims Should Be Dismissed.

Retailer Plaintiffs' Section 1 claim under the rule of reason (Count II) fails because their Complaints do not allege facts consistent with the Settlement Agreement sufficient to plausibly establish the existence of a "large and unjustified" payment under *Actavis* and their claim for conspiracy to monopolize (Count III) fails due to the absence of any plausible allegations of specific intent to monopolize. To avoid repetition, and pursuant to Pretrial Order No. 1, Dkt. No. 20, Defendants incorporate by reference the arguments made in its brief in support of their Motion to Dismiss the Consolidated Amended Complaint by Direct Purchaser Plaintiffs, which apply with equal force to bar Retailer Plaintiffs' claims.

### C. Retailer Plaintiffs' Claims for Injunctive Relief Should Be Dismissed for Failure to Allege Ongoing Illegal Conduct and Future Harm.

Both Section 16 of the Clayton Act, pursuant to which Retailer Plaintiffs seek an injunction, and the limitations on constitutional standing under Article III require that plaintiffs plausibly allege a threat of future harm from ongoing illegal conduct in order to seek an injunction. 15 U.S.C. § 26 ("Any person, firm, corporation, or association shall be entitled to sue for and have injunctive relief . . . against *threatened loss or damage* by a violation of the antitrust laws . . . ." (emphasis added)); *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 130 (1969) (plaintiff seeking an injunction under Section 16 of the Clayton Act must "demonstrate a significant threat of injury from an impending violation of the antitrust laws or from a contemporary violation likely to continue or recur"); *see also Abbott v. Pastides*, 900 F.3d 160, 176 (4th Cir. 2018) ("a plaintiff seeking prospective injunctive relief 'may not rely on prior harm' to establish Article III standing . . . but must instead 'establish ongoing or future injury in fact'" (citations omitted)).

Retailer Plaintiffs ask the Court for an injunction (1) preventing Defendants from "continuing their illegal conduct," (2) requiring Defendants to take unspecified "affirmative steps to dissipate the continuing effects of their prior unlawful conduct," and (3) preventing Defendants from "engaging in future anticompetitive conduct" concerning undefined "other generic drugs." *See, e.g.*, Walgreen Compl. ¶ 251. None of these requests is adequate to state a claim for injunctive relief.

### 1. Retailer Plaintiffs Cannot Obtain an Injunction Against Conduct that Has Ceased.

Retailers Plaintiffs' first request seeks an injunction against Defendants' "continuing their illegal conduct" and against that conduct's "continuing effects." *See, e.g.*, Walgreen Compl. ¶ 251. But Defendants are not *engaged* in any illegal conduct. By Retailer Plaintiffs' own account, Generic Zetia has been available to consumers since December 12, 2016, when Glenmark launched its Generic Zetia product. Walgreens Compl. ¶ 199; Rite Aid Compl. ¶ 197; CVS Compl. ¶ 197. Retailer Plaintiffs also expressly allege that "by July of 2017 there were *six generics* available on the market in addition to branded Zetia, and by September 2017 there were *eight generics* in addition to branded tablets." Walgreens Compl. ¶ 205 (emphases added); *see also* Rite Aid Compl. ¶ 203; CVS Compl. ¶ 203. In other words, Retailer Plaintiffs have alleged ongoing pervasive *competition*, not the threat of future anticompetitive harm.

Retailer Plaintiffs allege that despite the fact that there are now eight generics competing with Zetia, "Plaintiff continues to pay overcharges on their purchases of both branded and generic Zetia and will continue to pay such overcharges for some time in the future." CVS Compl. ¶ 217; see also Walgreen Compl. ¶ 218; Rite Aid Compl. ¶ 217. But that does not mean that there is any continuing conduct by Defendants that the Court could enjoin. The relevant patent has expired and Merck is not taking action to keep generics out of the market, so there is

nothing to enjoin. See United Food & Commercial Workers Unions & Emp'rs Midwest Health Benefits Fund v. Novartis Pharm. Corp., No. 15-cv-12732, 2017 WL 2837002, at \*1 (D. Mass. June 30, 2017), aff'd, 902 F.3d 1 (1st Cir. 2018) (finding that "while the motions were pending, a generic form of Gleevec was introduced into the market, thus mooting the request for injunctive relief" (emphasis added)); United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc., No. 14-md-02521, 2015 WL 4397396, at \*3 (N.D. Cal. July 17, 2015) (dismissing request for injunctive relief because "Defendants' anticompetitive conduct ended . . . when generic drug competitors were able to enter the market"). As such, Retailer Plaintiffs' claims for injunctive relief should be dismissed.

To the extent Retailer Plaintiffs seriously contend that Defendants can be required by a court injunction to "take affirmative steps to dissipate the continuing effects of their prior unlawful conduct," see, e.g., Walgreen Compl. ¶ 251, they have failed to plead a basis for such extraordinary mandatory relief. Requests for mandatory injunctive relief that would alter the status quo are subject to "a more exacting standard of review" and are "not favored unless the facts and law clearly support the moving party." Tiffany v. Forbes Custom Boats, Inc., 959 F.2d 232 (4th Cir. 1992), corrected (Apr. 27, 1992) (quoting Doe v. New York Univ., 666 F.2d 761, 773 (2d Cir. 1981)); see also Citizens Concerned for Separation of Church & State v. City & Cty. of Denver, 628 F.2d 1289, 1299 (10th Cir. 1980) (describing as "fundamental" the principle that "mandatory injunctive relief should be granted only under compelling circumstances inasmuch as it is a harsh remedial process not favored by the courts"). Retailer Plaintiffs have not offered any compelling circumstances to justify the extraordinary relief they seek, which appears likely to embroil the Court in regulating the prices in a concededly competitive market.

# 2. Retailer Plaintiffs Cannot Obtain an Injunction Against Vaguely Defined and Speculative Future Conduct.

Retailer Plaintiffs' allegation that the Court "has authority to enjoin Defendants from engaging in future reverse-payment agreements" is also incorrect and the request for such an injunction should be dismissed. Walgreen Compl. ¶ 219; Rite Aid Compl. ¶ 218; CVS Compl. ¶ 218. Retailer Plaintiffs do not allege any plausible likelihood of future harm concerning any generic drug. To obtain an injunction, the plaintiff must allege more than a mere possibility of harm—the plaintiff must show "some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive." *United States v. W. T. Grant Co.*, 345 U.S. 629, 633 (1953). For an injunction to be proper, "[t]he party seeking the injunction 'must satisfy the court that relief is needed." *NLRB v. Greensboro News & Record, Inc.*, 843 F.2d 795, 798 (4th Cir. 1988) (citing *W. T. Grant Co.*, 345 U.S. at 633).

Yet Retailer Plaintiffs do not specify any particular drug that could be the focal point of similar conduct in the future. Retailer Plaintiffs also ignore the Supreme Court's recognition, discussed above, that reverse payment settlements are not necessarily anti-competitive; that is why they are subject to the rule of reason. Given that Retailer Plaintiffs do not allege the drug or the payment that it seeks to enjoin, it is impossible to know whether the injunction Retailer Plaintiffs may seek to enjoin pro-competitive behavior.

Courts have rejected this type of request for an amorphous injunction against unspecified future conduct. For example, in *In re DDAVP Indirect Purchaser Antitrust Litig.*, 903 F. Supp. 2d 198, 210-11 (S.D.N.Y. 2012), the court dismissed a claim for injunctive relief where the "Plaintiffs . . . failed to demonstrate which drugs might be involved, or what fraudulent conduct might be undertaken, or which Plaintiffs might buy the drugs at supra-competitive prices." The "Plaintiffs' claim of future injury [was] wholly speculative [and] Putative class claims for an

injunction fail where they do not demonstrate a threat of future injury to the plaintiffs in the case." *Id.* Similarly, in *In re Plavix Indirect Purchaser Antitrust Litig.*, No. 06-cv-226, 2011 WL 335034, at \*4 (S.D. Ohio Jan. 31, 2011), the court dismissed a request for an injunction where the "Plaintiffs [went] so far as to request to enjoin Defendants from the possibility of entering into a yet-to-be-determined reverse payment agreement on some yet unidentified drug." According to the court, such a request was "too speculative a basis for injunctive relief." *Id.* At bottom, Retailer Plaintiffs' allegations fall far short of demonstrating "real and immediate" harm and are instead purely "conjectural" and "hypothetical." *Lyons*, 461 U.S. at 102 (1983).

The pitfalls of Retailer Plaintiffs' request for injunctive relief are apparent when considering the form a possible injunction would take. Any injunction issued by this Court would need to be "specific in terms" and "reasonable in detail." *See* Fed. R. Civ. P. 65(d). Merely proscribing conduct that has "similar purpose or effect" will not meet this standard. *See Fed. Election Comm'n v. Furgatch*, 869 F.2d 1256, 1263 (9th Cir. 1989) (holding as vague an injunction that permanently enjoined defendants "from future similar violations"). With no allegations suggesting any particularized threat of any harm, the Court should abstain from the abstract exercise of imagining future conduct to proscribe.

### III. CONCLUSION

For the foregoing reasons, and for the reasons described in Glenmark's DPP Motion to Dismiss, each of the Retailer Plaintiffs' Complaints fails to state a claim for relief and should be dismissed with prejudice.

DATED: October 11, 2018

Respectfully submitted,

#### /s/ J. Kevin Fee

J. Kevin Fee (Bar No. 88376) Teri J. Diaz (Bar No. 87457) MORGAN, LEWIS & BOCKIUS LLP 1111 Pennsylvania Ave., NW Washington, D.C. 20005

Tel: 202.739.3000 Fax: 202.739.3001

kevin.fee@morganlewis.com teri.diaz@morganlewis.com

Steven A. Reed (admitted *pro hac vice*)
R. Brendan Fee (admitted *pro hac vice*)
Zachary M. Johns (admitted *pro hac vice*)
Jessica J. Taticchi (admitted *pro hac vice*)
MORGAN, LEWIS & BOCKIUS LLP

1701 Market Street Philadelphia, PA 19103 Tel: 215.963.5000

Fax: 215.963.5001 steven.reed@morganlewis.com brendan.fee@morganlewis.com zachary.johns@morganlewis.com jessica.taticchi@morganlewis.com

Stacey Anne Mahoney (admitted *pro hac vice*)

MORGAN, LEWIS & BOCKIUS LLP

101 Park Ave.

New York, NY 10178 Tel: 212.309.6000 Fax: 212.309.6001

stacey. mahoney @morgan lewis. com

Counsel for Defendants Glenmark Pharmaceuticals, Ltd. and Glenmark Pharmaceuticals Inc., USA incorrectly identified as Glenmark Generics Inc., USA

### /s/ Stephen E. Noona

Stephen E. Noona Virginia State Bar No. 25367 KAUFMAN & CANOLES, P.C. 150 W. Main Street, Suite 2100 Norfolk, VA 23510-1665 Telephone: (757) 624-3239 Facsimile: (888) 360-9092 senoona@kaufcan.com

Samuel G. Liversidge (pro hac vice)
Christopher D. Dusseault (pro hac vice)
Michael M. Lee (pro hac vice)
GIBSON, DUNN & CRUTCHER LLP
333 South Grand Avenue
Los Angeles, CA 90071-3197
Telephone: (213) 229-7855
Facsimile: (213) 229-6855
Sliversidge@gibsondunn.com
CDusseault@gibsondunn.com
MLee@gibsondunn.com

Veronica S. Lewis (*pro hac vice*) GIBSON, DUNN & CRUTCHER LLP 2100 McKinney Avenue Dallas, TX 75201-6912 Telephone: (214) 698-3320 Facsimile: (214) 571-2936 vlewis@gibsondunn.com

Eric J. Stock (pro hac vice)
GIBSON, DUNN & CRUTCHER LLP
200 Park Avenue
New York, NY 10166
Telephone: (212) 351-2301
Facsimile: (212) 716-0801
estock@gibsondunn.com

Tarek Ismail (pro hac vice)
Jennifer L. Greenblatt (pro hac vice)
GOLDMAN ISMAIL TOMASELLI BRENNAN &
BAUM LLP

564 West Randolph Street, Suite 400 Chicago, IL 60661 Telephone: (312) 681-6000 Facsimile: (312) 881-5191 tismail@goldmanismail.com jgreenblatt@goldmanismail.com

Counsel for Defendants Merck & Co., Inc., Merck Sharp & Dohme Corp., Schering-Plough Corp., Schering Corp., MSP Singapore Co. LLC